**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-20-0666; Docket No. CDC-2020-0065]**

# Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the CDC's National Healthcare Safety Network (NHSN). NHSN is a public health surveillance system that collects, analyzes, reports, and makes available data for monitoring, measuring, and responding to healthcare associated infections (HAIs), antimicrobial use and resistance, blood transfusion safety events, and the extent to which healthcare facilities adhere to infection prevention practices and antimicrobial stewardship.

**DATES:** CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2020-0065 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666) - Revision – National Center for Emerging and Zoonotic Infection Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666. NHSN provides facilities, states, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various healthcare-associated infection prevention practice methods such

as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

NHSN currently has six components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), and the Dialysis Component. NHSN's planned Neonatal Component is expected to launch during the winter of 2020/2021. This component will focus on premature neonates and the healthcare-associated events that occur as a result of their prematurity. This component will be released with one module, which includes Late Onset-Sepsis and Meningitis. Late-onset sepsis (LOS) and Meningitis are common complications of extreme prematurity. These infections are usually serious, causing a prolongation of hospital stay, increased cost, and risk of morbidity and mortality. The data for this module will be electronically submitted, and manual data entry will not be available. This will allow more hospital personnel to be available to care for patients and will reduce annual burden across healthcare facilities. Additionally, LOS data will be utilized for prevention initiatives.

Data reported under the Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention

practices. Data will help detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance and to better understand the relationship of antimicrobial therapy to this rising problem.

Approved as a New Emergency ICR (National Healthcare Safety Network (NHSN) Patient Impact Module for Coronavirus (COVID-19) Surveillance in Healthcare Facilities, OMB Control No. 0920-1290), NHSN launched a COVID-19 Module in the Patient Safety Component on March 27th, 2020. This Module is designed to collect facility-level COVID-19 data on cases, deaths, capacity, healthcare worker staffing shortages, and personal protective equipment and supplies from hospitals on a daily basis. Facility-level data collected through NSHN as part of the COVID-19 Module are being made available to a broader set of Federal, state, and local agency data users than data typically collected by NHSN. Specifically, COVID-19 data at the state, county, territory, and facility level submitted to NHSN will continue to be used for public health emergency response activities by CDC's emergency COVID-19 response, by the U.S. Department of Health and Human Services' (HHS') COVID-19 tracking system maintained in the Office of the Assistant Secretary of Preparedness and Response as part of the National Response Coordination Center at

the Federal Emergency Management Agency (FEMA), and by the White House Coronavirus Task Force.

Under the Healthcare Personnel Safety Component, protocols and data on events—both positive and adverse—are used to determine (1) the magnitude of adverse events in healthcare personnel, and (2) compliance with immunization and sharps injuries safety guidelines. Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are reported and analyzed to provide national estimates of adverse reactions and incidents. Under the Long-Term Care Facility Component, data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the PS Component as a model with modifications to specifically address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN. A new form has been introduced for field testing- Respiratory Tract Infection (RTI) – not to be used by NHSN users, but as part of an EIP project with 4 EIP sites. Form title will be *Denominators for Healthcare Associated Infections (HAIs): Respiratory Tract Infections.* The purpose of this form is to allow testing prior to introducing a new module and forms to NHSN users. The CDC's Epidemiology Research & Innovations Branch (ERIB) team will use the form to perform field testing of variables to explore the utilization,

applicability, and data collection burden associated with these variables. This process will inform areas of improvement prior to incorporating the new module, including protocol, forms, and instructions into NHSN. The estimated burden for this form is 20 minutes, which is based on a similar denominator form. Also approved under New Emergency ICR 0920-1290, NHSN launched a COVID-19 Module in the Long-Term Care Component April 27th, 2020. As with the COVID-19 Module in the PS Component, the LTC COVID-19 Module is designed to collect facility-level COVID-19 data on cases, deaths, capacity, healthcare worker staffing shortages, and personal protective equipment and supplies from long-term care facilities on at least a weekly basis. Facility-level data collected through NSHN as part of the COVID-19 Module are being made available to a broader set of Federal, state, and local agency data users than data typically collected by NHSN. Specifically, COVID-19 data at the state, county, territory, and facility level submitted to NHSN will continue to be used for public health emergency response activities by CDC's emergency COVID-19 response, by the U.S. Department of Health and Human Services' (HHS') COVID-19 tracking system maintained in the Office of the Assistant Secretary of Preparedness and Response as part of the National Response Coordination Center at the Federal Emergency Management Agency (FEMA), and by the White House Coronavirus Task Force.

The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analyses processes as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities. The Outpatient Procedure Component (OPC) gathers data on the impact of infections and outcomes related to operative procedures performed in Ambulatory Surgery Centers (ASCs). The OPC is used to monitor two event types: Same Day Outcome Measures and Surgical Site Infections (SSIs).

NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the states. As of April 2020, 36 states, the District of Columbia and the City of Philadelphia, Pennsylvania have opted to use NHSN as their primary system for mandated reporting. Reporting compliance is completed by healthcare facilities in their respective jurisdictions, with emphasis on those states and municipalities acquiring varying consequences for failure to use NHSN. Additionally, healthcare facilities in five U.S. territories (Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and the Northern Mariana Islands) are voluntarily reporting to NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes.

NHSN’s data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect

patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities across the US and surrounding territories, and members of the public may use some protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities. CMS collects some HAI data and healthcare personnel influenza vaccination summary data, which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a federal mandate. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment. Still,

many healthcare facilities, even in states without HAI reporting legislation, submit limited HAI data to NHSN voluntarily. NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS' quality reporting programs. Additionally, CDC has collaborated with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation. This project has resulted in a significant increase in long-term care facilities reporting to NHSN.

The ICR previously approved in December of 2019 for 5,352,360 responses; 3,113,631 burden hours. The proposed changes in this new ICR include revisions to eight data collection forms and the addition of ten new forms for a total of 86 proposed data collection forms. In this Revision, CDC requests OMB approval for an estimated 2,365,743 annual burden hours.

Estimated Annualized Burden Hours

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| 57.100 NHSN Registration Form | 2,000 | 1 | 5/60 | 167 |
| 57.101 Facility Contact Information | 2,000 | 1 | 10/60 | 333 |
| 57.103 Patient Safety Component--Annual | 6765 | 1 | 55/60 | 6,201 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| Hospital Survey | | | | |
| 57.105 Group Contact Information | 1,000 | 1 | 5/60 | 83 |
| 57.106 Patient Safety Monthly Reporting Plan | 7,821 | 12 | 15/60 | 23,463 |
| 57.108 Primary Bloodstream Infection (BSI) | 5,775 | 5 | 38/60 | 18,288 |
| 57.111 Pneumonia (PNEU) | 1,800 | 2 | 30/60 | 18,288 |
| 57.112 Ventilator-Associated Event | 5,463 | 8 | 28/60 | 20,395 |
| 57.113 Pediatric Ventilator-Associated Event (PedVAE) | 334 | 1 | 30/60 | 167 |
| 57.114 Urinary Tract Infection (UTI) | 6,000 | 5 | 20/60 | 10,000 |
| 57.115 Custom Event | 600 | 91 | 35/60 | 31,850 |
| 57.116 Denominators for Neonatal Intensive Care Unit (NICU) | 1,100 | 12 | 4/60 | 880 |
| 57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC) | 500 | 12 | 5/60 | 503 |
| 57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA) | 5,500 | 60 | 5/60 | 27,665 |
| 57.120 Surgical Site Infection (SSI) | 6,000 | 9 | 35/60 | 31,500 |
| 57.121 Denominator for Procedure | 6,000 | 602 | 10/60 | 602,000 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| 57.122 HAI Progress Report State Health Department Survey | 55 | 1 | 28/60 | 26 |
| 57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables | 2,500 | 12 | 5/60 | 1,500 |
| 57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables | 2,000 | 12 | 5/60 | 2,000 |
| 57.125 Central Line Insertion Practices Adherence Monitoring | 500 | 213 | 25/60 | 44,375 |
| 57.126 MDRO or CDI Infection Form | 720 | 12 | 30/60 | 3,960 |
| ,.57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring | 5,500 | 29 | 15/60 | 39,875 |
| 57.128 Laboratory-identified MDRO or CDI Event | 4,800 | 79 | 20/60 | 126,400 |
| 57.129 Adult Sepsis | 50 | 250 | 25/60 | 5,208 |
| 57.130 COVID-19 Module: Patient Impact and Hospital Capacity | 3117 | 540 | 25/60 | 701,325 |
| 57.131 COVID-19 Module: Healthcare Worker Staffing | 3117 | 540 | 25/60 | 701,325 |
| 57.132 COVID-19 Module: Supplies | 3117 | 540 | 25/60 | 701,325 |
| 57.135 Late Onset Sepsis/ Meningitis Denominator Form: | 300 | 12 | 5/60 | 300 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| Data Table for monthly electronic upload | | | | |
| 57.136 Late Onset Sepsis/ Meningitis Event Form: Data Table for Monthly Electronic Upload | 300 | 4 | 5/60 | 100 |
| 57.137 Long-Term Care Facility Component – Annual Facility Survey | 3079 | 1 | 1/60 | 51 |
| 57.138 Laboratory-identified MDRO or CDI Event for LTCF | 1998 | 24 | 12/60 | 9,590 |
| 57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF | 1998 | 12 | 12/60 | 4,795 |
| 57.140 Urinary Tract Infection (UTI) for LTCF | 339 | 12 | 12/60 | 814 |
| 57.141 Monthly Reporting Plan for LTCF | 2011 | 12 | 12/60 | 4,826 |
| 57.142 Denominators for LTCF Locations | 339 | 12 | 250/60 | 814 |
| 57.143 Prevention Process Measures Monthly Monitoring for LTCF | 130 | 12 | 12/60 | 312 |
| 57.144 LTCF COVID-19 Module: Resident Impact and Facility Capacity | 14,674 | 26 | 20/60 | 127,175 |
| 57.145 LTCF COVID-19 Module: Staff and Personnel Impact | 14,674 | 26 | 15/60 | 95,381 |
| 57.146 LTCF COVID-19 Module: Supplies and PPE | 14,674 | 26 | 5/60 | 31,794 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| 57.147 LTCF COVID-19 Module: Ventilator Capacity and Supplies | 14,674 | 26 | 5/60 | 31,794 |
| 57.150 LTAC Annual Survey | 620 | 1 | 10/60 | 10 |
| 57.151 Rehab Annual Survey | 1,340 | 1 | 10/60 | 625 |
| 57.200 Healthcare Personnel Safety Component Annual Facility Survey | 50 | 1 | 480/60 | 400 |
| 57.203 Healthcare Personnel Safety Monthly Reporting Plan | - | 1 | 5/60 | - |
| 57.204 Healthcare Worker Demographic Data | 50 | 200 | 20/60 | 3,333 |
| 57.205 Exposure to Blood/Body Fluids | 50 | 50 | 60/60 | 2,500 |
| 57.206 Healthcare Worker Prophylaxis/Treatment | 50 | 30 | 15/60 | 375 |
| 57.207 Follow-Up Laboratory Testing | 50 | 50 | 15/60 | 625 |
| 57.210 Healthcare Worker Prophylaxis/Treatment -Influenza | 50 | 50 | 10/60 | 417 |
| 57.300 Hemovigilance Module Annual Survey | 500 | 1 | 85/60 | 708 |
| 57.301 Hemovigilance Module Monthly Reporting Plan | 500 | 12 | 1/60 | 100 |
| 57.303 Hemovigilance Module Monthly Reporting Denominators | 500 | 12 | 70/60 | 7,000 |
| 57.305 Hemovigilance Incident | 500 | 10 | 10/60 | 833 |
| 57.306 Hemovigilance | | 1 | 35/60 | 292 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| Module Annual Survey - Non-acute care facility | 500 | | | |
| 57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction | 500 | 4 | 20/60 | 667 |
| 57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction | 500 | 4 | 20/60 | 667 |
| 57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction | 500 | 1 | 20/60 | 167 |
| 57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction | 500 | 2 | 20/60 | 333 |
| 57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction | 500 | 4 | 20/60 | 667 |
| 57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction | 500 | 1 | 20/60 | 167 |
| 57.313 Hemovigilance Adverse Reaction – Infection | 500 | 1 | 20/60 | 167 |
| 57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura | 500 | 1 | 20/60 | 167 |
| 57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea | 500 | 1 | 20/60 | 167 |
| 57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. | 500 | 1 | 20/60 | 167 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| Host Disease | | | | |
| 57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury | 500 | 1 | 20/60 | 167 |
| 57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload | 500 | 2 | 20/60 | 333 |
| 57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction | 500 | 1 | 20/60 | 167 |
| 57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction | 500 | 1 | 20/60 | 167 |
| 57.400 Outpatient Procedure Component—Annual Facility Survey | 700 | 1 | 10/60 | 117 |
| 57.401 Outpatient Procedure Component - Monthly Reporting Plan | 700 | 12 | 15/60 | 2,100 |
| 57.402 Outpatient Procedure Component Same Day Outcome Measures | 200 | 1 | 40/60 | 133 |
| 57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures | 200 | 400 | 40/60 | 53,333 |
| 57.404 Outpatient Procedure Component – SSI Denominator | 700 | 100 | 40/60 | 46,667 |
| 57.405 Outpatient Procedure Component - Surgical Site (SSI) Event | 700 | 5 | 40/60 | 2,333 |

| Form Number & Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (Min./Hour) | Total Burden (Hours) |
|---|---|---|---|---|
| 57.500 Outpatient Dialysis Center Practices Survey | 7,200 | 1 | 127/60 | 15,240 |
| 57.501 Dialysis Monthly Reporting Plan | 7,200 | 12 | 5/60 | 7,200 |
| 57.502 Dialysis Event | 7,200 | 30 | 25/60 | 90,000 |
| 57.503 Denominator for Outpatient Dialysis | 7,200 | 30 | 10/60 | 14,400 |
| 57.504 Prevention Process Measures Monthly Monitoring for Dialysis | 1,730 | 12 | 75/60 | 25,950 |
| 57.505 Dialysis Patient Influenza Vaccination | 615 | 50 | 10/60 | 5,125 |
| 57.506 Dialysis Patient Influenza Vaccination Denominator | 615 | 5 | 10/60 | 513 |
| 57.507 Home Dialysis Center Practices Survey | 430 | 1 | 30/60 | 215 |
| Total | | | | 2,365,743 |

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